



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0455]

Revocation of Authorization of Emergency Use of a Medical Device During COVID-19;

Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Battelle Memorial Institute for the Battelle Critical Care Decontamination System. FDA revoked the Authorization on April 30, 2021, under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by Battelle Memorial Institute on April 2, 2021. The revocation, which includes an explanation of the reasons for the revocation, is reprinted in this document.

**DATES:** The Authorization for the Battelle Critical Care Decontamination System is revoked as of April 30, 2021.

**ADDRESSES:** Submit written requests for a single copy of the revocation to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocation may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the revocation.

**FOR FURTHER INFORMATION CONTACT:** Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 240-402-8155 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On March 28, 2020, FDA issued the Authorization to Battelle Memorial Institute for the Battelle Critical Care Decontamination System. Notice of the issuance of the Authorization was published in the *Federal Register* on June 5, 2020 (85 FR 34638), as required by section 564(h)(1) of the FD&C Act. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

## II. EUA Revocation Request for a Medical Device During COVID-19

On April 2, 2021, Battelle Memorial Institute requested the revocation of, and on April 30, 2021, FDA revoked, the Authorization for the Battelle Critical Care Decontamination System. Because Battelle Memorial Institute notified FDA that it has ceased operations and associated activities and requests withdrawal of the Authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

## III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at <https://www.regulations.gov/> and <https://www.fda.gov/media/148132/download>.

## IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA for the Battelle Critical Care

Decontamination System. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.



April 30, 2021

Mr. Jeff Rose  
Battelle Memorial Institute  
505 King Avenue  
Columbus, OH 43201

**Re: Revocation of EUA200210**

Dear Mr. Rose:

This letter is in response to Battelle Memorial Institute's (Battelle's) request dated April 2, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA200210) for the Battelle Critical Care Decontamination System (hereafter referred to as "Battelle Decontamination System") issued on March 28, 2020, and revised and reissued on March 29, 2020, June 6, 2020, and January 21, 2021. In its request, Battelle confirmed that it has ceased operation of all Battelle Decontamination System sites as well as associated marketing activities.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when the criteria under section 564(c) of the Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Battelle has notified FDA that it has ceased operations and associated activities and requests withdrawal of the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA200210 for the Battelle Decontamination System, pursuant to and section 564(g)(2)(C) of the Act. As of the date of this letter, the Battelle Decontamination System is no longer authorized for emergency use by FDA.

FDA encourages Battelle to inform its customers of this revocation.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

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RADM Denise M. Hinton  
Chief Scientist  
Food and Drug Administration

Dated: May 24, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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